IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

Jedidiah Murphy, Plaintiff,	:	
v.	:	Case No. 23-cv-1199
Bobby Lumpkin, Director of Correctional Institutions, Texas Dept. of Criminal Justice,	:	**THIS IS A CAPITAL CASE**
Kelly Strong, Warden, Texas State Penitentiary Huntsville Unit,	:	**EXECUTION SET FOR OCTOBER 10, 2023**
Bryan Collier, Executive Director, Texas Dept. of Criminal Justice,	:	
Defendants.	:	

EXHIBITS TO COMPLAINT

VOL. 2

Exhibits 7-12

EXHIBIT 7

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Research Article

Stability-Indicating Assay for the Determination of Pentobarbital Sodium in Liquid Formulations

Myriam Ajemni, Issa-Bella Balde, Sofiane Kabiche, Sandra Carret, Jean-Eudes Fontan, Salvatore Cisternino, and Joël Schlatter

Service Pharmacie, AP-HP Hôpital Jean-Verdier, Hôpitaux Universitaires de Paris-Seine-Saint-Denis, Avenue du 14 juillet, 93140 Bondy, France

Correspondence should be addressed to Joël Schlatter; joel.schlatter@aphp.fr

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A stability-indicating assay by reversed-phase high performance liquid chromatography (RP-HPLC) method was developed for the determination of pentobarbital sodium in oral formulations: a drug used for infant sedation in computed tomography (CT) or magnetic resonance imaging (MRI) scan. The chromatographic separation was achieved on a reversed-phase C18 column, using isocratic elution and a detector set at 214 nm. The optimized mobile phase consisted of a 0.01 M potassium buffer pH 3 and methanol (40 : 60, v/v). The flow rate was 1.0 mL/min and the run time of analysis was 5 min. The linearity of the method was demonstrated in the range of 5 to 250 μg/mL pentobarbital sodium solution (r^2 = 0.999). The limit of detection and limit of quantification were 2.10 and 3.97 μg/mL, respectively. The intraday and interday precisions were less than 2.1%. Accuracy of the method ranged from 99.2 to 101.3%. Stability studies indicate that the drug is stable to sunlight and in aqueous solution. Accelerated pentobarbital sodium breakdown by strong alkaline, acidic, or oxidative stress produced noninterfering peaks. This method allows accurate and reliable determination of pentobarbital sodium for drug stability assay in pharmaceutical studies.

1. Introduction

Pentobarbital sodium (5-ethyl-5-(1-methylbutyl)-2,4,6(1H, 3H,5H)-pyrimidinetrione, sodium) is a psychoactive drug with short-acting sedative effects in adult and paediatric patients. However, it is not any longer marketed in Europe and in the United States. European drug agencies recently withdraw chloral hydrate, a widely used sedative drug, due to its adverse effects such as mutagenesis [1]. Pentobarbital sodium would be an alternative in paediatric sedative procedures such as in computed tomography or magnetic resonance imaging in infants. Clinical studies reported the effectiveness of pentobarbital sodium sedation and a decreased rate of adverse events as compared to chloral hydrate preimaging procedure [2–4]. Both drugs may also produce similar side effects including decreased oxygen saturation, vomiting, and respiratory depression [2–5]. The initial oral dose of sodium pentobarbital in sedation procedure for infants is usually 4-5 mg/kg with a maximum of 8 mg/kg. If the sedative response is not achieved, one additional 2 mg/kg oral dose can be administered [6]. A literature survey showed that only one liquid chromatography (HPLC) method is reported for the quantitative determination of pentobarbital sodium and some impurities in bulk drug substance and dosage forms with a chromatographic run of 30 min [7]. Drug crystallization could occur in 24 h when the pentobarbital sodium 50 mg/mL in 0.9% sodium chloride solution was further diluted to 10 mg/mL in repackaging polypropylene syringe [8]. More recently, Priest and Geisbuhler reported that injectable pentobarbital sodium was not degraded when stored in dark at room temperature using the HPLC method previously cited [9]. Here, we report a precise, accurate, and robust HPLC stability-indicating assay to assess pentobarbital sodium in oral/liquid compounding formulations which was validated for the first time with oxidative, alkali, and acidic breakdown and a chromatographic run time of 5 min. This assay was validated according to the International Conference on Harmonization [10].

2. Material and Method

2.1. Chemical and Reagents. Pharmaceutical pentobarbital sodium powder was supplied by Inresa (Bartenheim, France, lot 10026/1111B479). Phenobarbital sodium was used as an internal standard (IS) and was obtained from Sanofi Whintrop (Maisons-Alfort, France, lot 284). The compounding formulations Inorpha, Ora-Plus, Ora-Sweet, Ora-Sweet SF, Ora-Blend, and Ora-Blend SF were purchased from Inresa (Bartenheim, France, lots 4388549, 4469317, 4378457, 4287617, 4509679, and 4388553, resp.). The analytical grade methanol was obtained from Sigma-Aldrich (Chromasolv, St. Quentin Fallavier, France). Potassium dihydrogen phosphate was obtained from VWR Chemicals (Fontenay sous bois, France). Deionised water was purchased from Fresenius (Versylene, Sèvres, France).

2.2. HPLC Instrumentation and Conditions. The HPLC Dionex Ultimate 3000 system (Thermo Scientific, Villebon sur Yvette, France) contained an integrated solvent and degasser SRD-3200, an analytical pump HPG-3200SD, a thermostated autosampler WPS-3000TSL, a thermostated column compartment TCC-3000SD, and a diode array detector MWD-3000. Data acquisition (e.g., peak time and area) was carried out using in line Chromeleon software (v6.80 SP2) (Thermo Scientific). The eluent was monitored at 214 nm. Chromatographic separation was achieved at 25°C using a reverse phase Nova-Pak C18 column (60 Å, 4 μm, 4.6 mm × 150 mm, Waters, Guyancourt, France). The mobile phase (0.01 M phosphate buffer pH 3: methanol; 40 : 60 v/v) was pumped at a flow rate of 1.0 mL/min. The injection volume was set at 25 μL.

2.3. Preparation of Stock and Standards Solutions

2.3.1. Pentobarbital Sodium Stock and Working Solutions. Pentobarbital sodium stock solution (1 mg/mL) was prepared by accurately weighing 100 mg. Volume was made up to the mark with deionised water in 100 mL volumetric flask. A working solution (0.1 mg/mL) was prepared by dilution of the stock solution. The solutions were stored at 2–8°C for 5 days.

2.3.2. Preparation of the Internal Standard Solution. Phenobarbital sodium stock solution (1 mg/mL) was prepared by accurately weighing 100 mg. Volume was made up to the mark with deionised water in 100 mL volumetric flask. The stock solution was stored at 2–8°C for 5 days.

2.3.3. Calibration Standards. Calibration standards at 5, 10, 20, 50, 100, and 200 μg/mL were freshly prepared using either stock or working solution. These solutions contained IS at 20 μg/mL.

2.3.4. Quality Control Samples. Quality control solutions at 8, 15, 30, 80, and 150 μg/mL containing IS (20 μg/mL) were prepared extemporaneously.

2.4. Analytical Method Validation

2.4.1. Linearity. Appropriate volumes of pentobarbital sodium stock (1 mg/mL) and working (100 μg/mL) standard solutions were diluted with deionised water to yield 5, 10, 20, 50, 100, and 200 μg/mL. Six replicates of each concentration were independently prepared and injected into the chromatograph. The linearity was determined by calculating a regression line from the plot of the peak area ratios of the drug and IS versus concentrations of the drug. Regression analyses were computed for pentobarbital sodium with Chromeleon software. The method was evaluated by determination of the correlation coefficient and intercept values according to the ICH guidelines.

2.4.2. Limit of Detection and Limit of Quantification. Limit of detection (LOD) and limit of quantification (LOQ) of pentobarbital sodium assay were determined by calibration curve method. Solutions of pentobarbital sodium were prepared in linearity range and injected in triplicate. Average peak area of three analyses was plotted against concentration. LOD and LOQ were calculated by using the following equations: LOD = $(3.3 \times S_{yx})/b$, LOQ = $(10.0 \times S_{yx})/b$, where S_{yx} is residual variance due to regression; b is the slope.

2.4.3. Precision. The intraday precision was determined by measuring quality control samples of 8, 15, 30, 80, and 150 μg/mL of pentobarbital sodium, injected six times on the same day. The intermediate precision was estimated by injecting quality control samples prepared at the same concentrations on three different days by different operators. The peak area ratios of all injections were taken and standard deviation, % relative standard deviation (RSD), was calculated.

2.4.4. Accuracy. Accuracy is tested by the standard addition method at different levels: 25, 50, 80, 100, and 120%. The mean recovery of pentobarbital sodium of the target concentration (50 μg/mL) was calculated and accepted with 100 ± 2%.

2.4.5. Robustness. HPLC conditions were slightly modified to evaluate the analytical method robustness. These changes (see Table 1) included the flow rate, the detection wavelength, the column temperature, or the methanol proportion in the mobile phase.

2.4.6. Forced Degradation Study. Alkaline, acidic, and oxidative stress and direct exposure to sunlight were carried out as reported in Table 2. No internal standard was added in the forced degradation study.

(1) Alkali Hydrolysis. Ten mL of pentobarbital stock solution was mixed in a flask with 1 N sodium hydroxide (4 mL) for 1 h at 50°C. Before analysis, the solution was cooled at room temperature and neutralized with hydrochloric acid. The solution was completed with deionised water to reach a targeted concentration of 50 μg/mL in a volumetric flask.

(2) Acid Hydrolysis. Ten mL of pentobarbital stock solution was mixed in a flask with 1 N hydrochloride acid (4 mL)

Table 1: Robustness.

Parameters	Modification	% recovery	R_s	T_f-D	T_f-IS	Plates
Flow rate (mL/min)	1.1	100.3	8.06	1.30	1.34	5503
	1.2	100.2	7.73	1.26	1.27	5155
	1.3	100.2	7.46	1.19	1.38	4779
Wavelength of detection (nm)	218	105.0	8.46	1.27	1.42	6042
	220	103.4	8.43	1.33	1.35	5969
	225	78.5	8.41	1.31	1.42	5848
Column temperature (°C)	25	100.1	8.22	1.30	1.46	5828
	27	100.1	8.02	1.35	1.34	5856
	30	100.0	7.80	1.36	1.32	5944
Methanol in mobile phase	−0.2%	100.0	8.42	1.33	1.38	6002
	+0.2%	100.0	7.33	1.39	1.42	5549

R_s: resolution; T_f-D: tailing factor of the drug; T_f-IS: tailing factor of the internal standard.

Table 2: Forced degradations studies.

Stress conditions	% remaining	% degradation	Retention time of degraded products
Acidic stress (1 N HCl, 50°C, 1 h)	102.2	—	0.0
High acidic stress (12 N HCl, 50°C, 48 h)	31.8	68.2	0.0
Alkaline stress (1 N NaOH, 50°C, 1 h)	98.4	1.6	0.0
High alkaline stress (10 N NaOH, 50°C, 48 h)	89.8	10.2	1.46, 1.81
Oxidative stress (3%, 50°C, 48 h)	50.9	49.1	1.44
Thermal stress (50°C, 5 days)	89.4	10.6	0.0
High thermal stress (100°C, 1 h)	19.9	80.1	0.0
Direct sunlight (48 h)	95.1	4.9	0.0
Aqueous stability (after 21 days)	99.7	0.3	0.0

for 1 h at 50°C. Before analysis, the solution was cooled at room temperature and neutralized with sodium hydroxide. The solution was completed with deionised water to reach a targeted concentration of 50 μg/mL in a volumetric flask.

(3) Oxidative Stress. Ten mL of the pentobarbital stock solution was mixed with 1 mL of 3% hydrogen peroxide and stored at 50°C for 1 h. The solution was cooled and completed with deionised water until the volumetric flask mark to reach a targeted concentration of 50 μg/mL.

(4) Sunlight Degradation. Ten mL of the pentobarbital stock solution was transferred into a 200 mL volumetric flask and exposed to direct sunlight for 5 days at room temperature. The solution was completed to the flask mark with deionised water.

(5) Thermal Degradation. Ten mL of stock solution was transferred into volumetric flask (200 mL) and kept in air dry oven at 105°C for 5 h. Then, the solution was cooled and completed to the flask mark with deionised water.

(6) Hydrolytic Degradation. Ten mL of pentobarbital stock solution was transferred into a volumetric flask and mixed with 10 mL of deionised water. The solution was heated on water bath for 1 h. Then, the solution was cooled and completed until the 200 mL flask mark with water to reach a hypothetical target concentration of 50 μg/mL.

3. Results and Discussion

3.1. Analytical Development Method. In order to achieve optimum separation, pentobarbital sodium and IS were injected into different mobile phase solutions mixing phosphate buffer and acetonitrile or phosphate buffer and methanol at different proportions, 70 : 30, 60 : 40, 50 : 50, and 40 : 60, and pH values, 7, 5, or 3. The retention time and tailing factor along with resolution factor were recorded. As the pKa of pentobarbital is reported to be 8.1, mobile phase with pH 3 was selected. Using the Nova-Pak C18 column, pentobarbital sodium and IS were eluted at 3.5 and 2.2 min, respectively. Column temperature (22–26°C) was found to be not a critical factor of this analysis. The optimum UV absorption of the drug was obtained at 214 nm as there was no interference from excipients present in oral compounding formulations. A typical chromatogram obtained with the present method is depicted in Figure 1.

3.2. Method Validation

3.2.1. Linearity. The linearity range of pentobarbital sodium was in the interval of 5–200 μg/mL. These were represented by a mean linear regression equation as follows: $y = 0.0291x + 0.0378$ with 0.9998 correlation coefficient and regression line was established by least squares method (Table 3).

Table 3: Linearity data of the developed method.

Initial conc. (μg/mL)	Mean peak area ± S.D. (pentobarbital) (n = 6)	Mean peak area (IS)	Mean peak ratio	Actual conc. (μg/mL)	% assay
5	4.285 ± 0.020	27.805 ± 0.192	0.154 ± 0.001	3.99 ± 1.29	79.8
10	8.637 ± 0.050	27.897 ± 0.284	0.310 ± 0.001	9.33 ± 1.29	93.3
20	17.098 ± 0.143	27.186 ± 1.093	0.630 ± 0.031	20.34 ± 1.19	101.7
50	42.565 ± 1.147	27.983 ± 0.376	1.521 ± 0.028	50.96 ± 1.20	101.9
100	83.084 ± 1.149	27.856 ± 0.111	2.983 ± 0.047	101.19 ± 1.14	101.2
200	164.194 ± 0.401	28.135 ± 0.253	5.836 ± 0.048	199.26 ± 1.13	99.6
$y = 0.0291x + 0.0378$, $r^2 = 0.9998$					

Table 4: Precision study of the method.

Nominal conc. (μg/mL)	Intraday precision			Interday precision		
	Calculated conc. (μg/mL), mean ± SD	Accuracy (%bias)	RSD	Calculated conc. (μg/mL), mean ± SD	Accuracy (%bias)	RSD
8	8.273 ± 0.009	3.42	0.11	8.181 ± 0.103	2.27	1.25
15	15.280 ± 0.143	1.86	0.94	15.052 ± 0.208	0.35	1.38
30	30.748 ± 0.632	2.49	2.06	30.355 ± 0.386	1.18	1.27
80	81.738 ± 0.602	2.17	0.74	81.257 ± 1,218	1.57	1.50
150	153.569 ± 0.328	2.38	0.21	152,278 ± 2,139	1.52	1.41

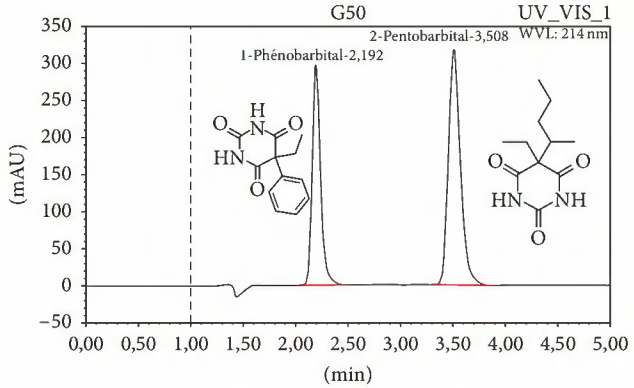

Figure 1: Typical chromatogram of pentobarbital sodium and internal standard and their chemical structures.

3.2.2. Limit of Detection (LOD) and Limit of Quantification (LOQ). The determined values of LOD and LOQ were 2.103 and 3.979 μg/mL calculated using slope and Y-intercept as per ICH guideline.

3.2.3. Precision. The results were obtained for the intraday and interday precision of the method, expressed as RSD values. As shown in the table, the intraday and interday RSD were <2.1% for all concentrations tested in different situations studied (Table 4).

3.2.4. Accuracy. The percentage recoveries were found to be 99.2 to 101.3% (Table 5). The results of the recovery studies undoubtedly demonstrate accuracy of the proposed method.

Table 5: Accuracy of the method.

Standard (μg/mL)	Added		Found (μg/mL)	% recovery	RSD
	%	μg/mL	Mean ± SD, n = 6	Mean ± SD	
50	25	62.5	63.29 ± 0.48	101.27 ± 0.77	0.77
50	50	75	74.78 ± 0.56	99.71 ± 0.75	0.75
50	80	90	89.55 ± 2.61	99.49 ± 2.90	2.90
50	100	100	99.23 ± 1.22	99.23 ± 1.22	1.22
50	120	110	110.59 ± 0.28	100.53 ± 0.25	0.25

3.2.5. Specificity. The specificity was estimated by spiking compounding vehicles as Ora-Plus, Ora-Sweet, Ora-Sweet SF, Ora-Blend, Ora-Blend SF, and Inorpha into a preweighed quantity of drug. The specificity study was carried out to check the interference from the excipients used in these vehicles. The chromatogram showed peak for pentobarbital sodium without any interfering peak.

3.2.6. Robustness. The robustness of the method was illustrated by getting the resolution (R_s), the tailing factor of the drug (T_f-D), the tailing factor of the internal standard (T_f-IS), and the number of plates when flow rate, wavelength detection, column temperature, and methanol proportion were slightly changed (Table 1). Table 1 shows that the percent recoveries of pentobarbital sodium were good under most conditions except for the wavelength condition at 225 nm. The deliberate changes in the method do not affect the resolution, tailing factors of drug and IS, and number of plates significantly (Table 1).

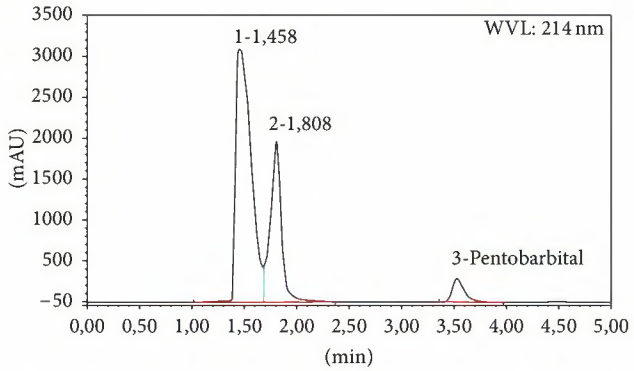

FIGURE 2: Chromatogram of 12 N NaOH treated pentobarbital sodium at 50°C for 48 h.

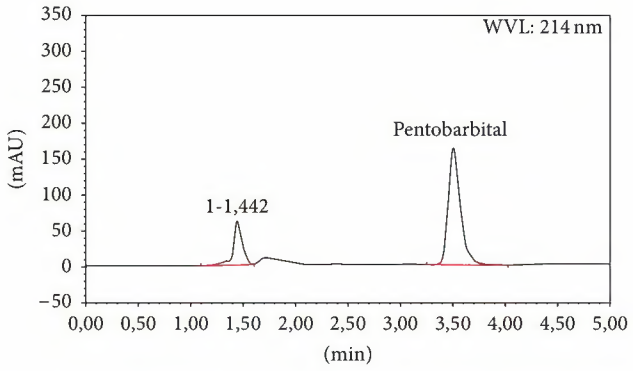

FIGURE 3: Chromatogram of 3% hydrogen peroxide treated pentobarbital sodium at 50°C for 48 h.

3.2.7. System Suitability Parameters. The system suitability tests were studied before performing the validation and the calculated parameters are within the acceptance criteria. The capacity factor was 1.39, the resolution was 7.65, the selectivity was 1.6, the number of theoretical plates was 5550, the tailing factor (T_f-D) of drug was 1.30, the tailing factor of internal standard (T_f-IS) was 1.35, and the RSD of repeatability of injection were <0.3%. Hence, the proposed method was successfully applied to routine analysis.

3.2.8. Stability of Sample. Stability of the sample solution was established by storage of the sample solution at refrigerator (2–8°C) for 21 days and at room temperature for 24 h. The results from the solution stability experiments confirmed that the sample solution was stable for up to 21 days at refrigerator and during assay determination.

3.2.9. Forced Degradation Study. Forced degradation studies were performed to demonstrate the stability-indicating capability of the proposed HPLC method (Table 2). No degradation of pentobarbital sodium exposed to 1 N HCl, 1 N NaOH, and direct sunlight was observed. Due to this particular stability, high acidic and alkaline stress conditions were performed using 10 N NaOH and 12 N HCl at 50°C for 48 h. A chromatogram of high alkaline hydrolysis performed at 50°C for 48 h showed degradation product peaks at retention times 1.46 and 1.81 min (Figure 2). A chromatogram of oxidative stress performed at 50°C for 48 h showed degradation product peak at retention time 1.44 min (Figure 3). The compound was stable at high temperature (50°C) and in aqueous solution. These statements are in agreement with the 6.5% loss of potency described by Gupta [8] in its pentobarbital preparation boiled for 1.5 h and the complete degradation of pentobarbital in 30 days using combination of high pH and 20% formaldehyde described by Gannet et al. [11].

4. Conclusion

This rapid and simple RP-HPLC method was successfully developed for the determination of pentobarbital sodium stability in water solution. The developed analytical method is precise, accurate, and linear. Forced degradation data proved that the method is specific for the analyte and free from the interference of blank and unknown degradation products. The method is suitable for the analysis of stability samples and the routine analysis of pentobarbital sodium in formulations.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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EXHIBT 8

See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04)

OMB APPROVAL No. 1117-0010

[redacted]

DATE 29 APRIL 19

LINE No.	TO BE FILLED IN BY PURCHASER: No. of Packages	Size of Package	Name of Item	NATIONAL DRUG CODE	TO BE FILLED IN BY PURCHASER: No. of Packages Received	Date Received
1	15	100mL	Pentobarbital Sodium Inj, 50mg/mL cmpd	[redacted]	15	04/29/19
2						
3						
4						
5						
6						
7						
8						
9						
10						

LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT [redacted]

Date Issued: 04/01/2016

DEA Registration No.: [redacted]

Name and Address of Registrant: [redacted]

Schedules: 2, 2N, 3, 3N, 4, 5,

Registered as a: CHAIN HOSP/CLINIC

No. of this Order Form: [redacted]

DEA Form - 222 (AUGUST 2011)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

PURCHASER'S Copy 3

[redacted]

See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

[redacted]

DATE: 08 Sep 20

TO BE FILLED IN BY SUPPLIER

[redacted]

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	1	10 9mL	Cap'l Pentobarbital Na Inj. 50mg/mL 100%	[redacted]	1	9/8/20
2						
3						
4						
5						
6						
7						
8						
9						
10						

1 ◀ LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT

[redacted]

Date Issued: 05/11/2011

DEA Registration No.: [redacted]

Name and Address of Registrant: [redacted]

Schedules: 2, 2N, 3, 3N, 4, 5,

Registered as a: RETAIL PHARMACY

No. of this Order Form: [redacted]

DEA Form -222 (JANUARY 2010)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

SUPPLIER'S Copy 1

[redacted]

See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

[redacted]

05 OCT 20

LINE No.	TO BE FILLED IN BY PURCHASER: No. of Packages	Size of Package	Name of Item	NATIONAL DRUG CODE	PURCHASER: No. of Packages Received	Date Received
1	1	50mL	Cmpd Pentobarbital Na Inj. 50mg/mL	[redacted]	1	10/05/20
2						
3						
4						
5						
6						
7						
8						
9						
10						

LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT [redacted]

Date Issued: 04/01/2016

DEA Registration No.: [redacted]

Name and Address of Registrant: [redacted]

Schedules: 2, 2N, 3, 3N, 4, 5,

Registered as a: CHAIN HOSP/CLINIC

No. of this Order Form: [redacted]

DEA Form - 222 (AUGUST 2011)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

PURCHASER'S Copy 3

C [redacted]

See Reverse of PURCHASER'S Copy for Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

[redacted]

3-18-2021

NATIO[redacted]

PURCHASER

LINE No.	TO BE FILLED IN BY PURCHASER: No. of Packages	Size of Package	Name of Item	Received	Date Received
1	9	50mL	Pentobarbital Sodium Inj 50mg/mL CMP[redacted]	9	3/18/21
2					
3					
4					
5					
6					
7					
8					
9					
10					

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT [redacted]

Date Issued	DEA Registration No.	Name and Address of Registrant
04/01/2016	[redacted]	[redacted]
Schedules: 2, 2N, 3, 3N, 4, 5,		
Registered as a: CHAIN HOSP/CLINIC	No. of this Order Form: [redacted]	

DEA Form - 222
(AUGUST 2011)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
PURCHASER'S Copy 3

C[redacted]

EXHIBIT 9

Huntsville Unit
Storage Inventory
Pentobarbital 50mg/ml (2.5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
6/10/20	Gutierrez, Ruben	999308	8	2		6	[redacted]
6/10/20	Return	999308	6		2	8	
7/8/20	Wardlow, Billy Joe	999137	8	2		6	
7/8/20	Wardlow, Billy Joe	999137	6		2	8	
10/5/20	Stock received	N/A	8		1	9	
11/2/20	Return to Supplier	N/A	9	1		8	
1/29/21	Remove from Stock	N/A	8	7		1	
2/23/21	Received from Supplier	N/A	1		1	2	
3/18/21	Received from Supplier	N/A	2		9	11	
4/21/21	Return to supplier	N/A	11	1		10	
5.19.21	Jones, Quintin	999379	10	2		8	
6.30.21	Hummel, John	999567	8	2		6	
9.8.21	Ramirez, John Henry	999544	6	2		4	
9.8.21	Ramirez - Return	999544	4		2	6	
9.28.21	Rhoades, Rick	999049	6	2		4	
9.28.21	Rhoades - Return	999049	4		2	6	
11/17/21	Removed from stock	N/A	6	1		5	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 50 ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
2/3/22	Return to Stock	N/A	5		1	6	[redacted]
4-21-22	Burton, C.	000993	6	2		4	
4-21-22	Return to Stock	N/A	4		2	6	
8-17-22	Chanthakoummane Kosoul	999529	6	2		4	
8-17-22	Return to Stock	N/A	4		2	6	
8-30-22	Return to Supplier	N/A	6	1		5	
9-30-22	Return to Supplier	N/A	5	1		4	
10-5-22	Ramirez, John	999544	4	2		2	
10-5-22	Return to Stock	N/A	2		2	4	
11-9-22	Beatty, Tracy	999484	4	2		2	
11-9-22	Return to Stock	N/A	2		2	4	
11-14-22	Barbee	999507	4	2		2	
11-14-22	Return to Stock	N/A	2	2pc	2	4	
2-1-23	Ruiz Wesley	999536	4	2		2	
2-1-23	Returned to Stock	N/A	2		2	4	
2-8-23	Balentine, John	999315	4	2		2	
2-8-23	Returned to STOCK	N/A	2		2	4	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 50 mg/ml (2.5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
3-7-23	Green Gary	999561	4	2		2	[redacted]
3-7-23	Returned to Stock	N/A	2		2	4	
3-9-23	Brown Arthur	999110	4	2		2	
3-9-23	Return to Stock	N/A	2		2	4	
8-7-23	Return to Supplier	N/A	4	1		3	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

EXHIBIT 10

Huntsville Unit
Storage Inventory
Pentobarbital 100 ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
12/3/18	Begin New Form	—				11	[redacted]
12/4/18	Garcia Joseph	999441	11	2		9	
12/4/18	Return	999441	9		1	10	
12/11/18	Braziel, Alvin	999393	10	2		8	
12/11/18	Return	999393	8		1	9	
1/30/19	Jennings, Robert	000956	9	2		7	
1/30/19	Return	000956	7		1	8	
2/28/19	Coble, Billie	0000976	8	2		6	
2/28/19	Return	0000976	6		1	7	
3/28/19	Murphy, Patrick	999461	7	2		5	
3/28/19	Return	999467	5		2	7	
4/24/19	King, John	999295	7	2		5	
4/24/19	Return	999295	5		1	6	
4/29/19	Received from Supplier		6		15	21	
6-3-19	inv	inv	—	—	—	21	
7/10/19	inv	inv	—	—	—	21	
8/12/19	inv	inv	—	—	—	21	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 100 ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
8·21·19	Swearingen, Larry	999361	21	2		19	[redacted]
8·21·19	return	999361	19		1	20	
9·4·19	Crutsinger, Billy	999459	20	1		19	
9·4·19	Return	999361	19		1	20	
9·10·19	Soliz, Mark	999571	20	2		18	
9·10·19	Return	999571	18		1	19	
9·25·19	Sparks, Robert	999542	19	2		17	
9·25·19	Return, Sparks	999542	17		1	18	
11·6·19	Hall, Justen	999497	18	2		16	
11·6·19	Hall, Justen	999497	16		1	17	
12·11·19	Runnels, Travis	999505	17	2		15	
12·11·19	Runnels, Travis return	999505	15		1	16	
1·15·20	Gardner, John	999514	16	2		14	
1·15·20	Gardner- return	999516	14		1	15	
2·6·20	Ochoa, Abel	999450	15	1		14	
2·6·20	Ochoa, return	999450	14		1	15	
5/6/20	expired		15	1		14	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 100 ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
4/10/20	Gutierrez, Ruben	999308	14	1		13	[redacted]
4/14/20	Return	999308	13		1	14	
7/8/20	Wardlow, Billy Joe	999137	14	1		13	
7/8/20	Return-no	999137	13			13	
9/8/20	Return to Supplier	N/A	13	1		12	
1/21/21	Return	N/A	12		1	13	
1/21/21	Return to Supplier	N/A	13	1		12	
5-19-21	Jones, Quintin	999379	12	1		11	
5-19-21	Jones - Return	999379	11		1	12	
6.30.21	Hummel, John	999567	12	1		11	
6.30.21	Hummel, Return	999567	11		1	12	
9.8.21	Ramirez, John Henry	999544	12	1		11	
9.8.21	Ramirez - Return	999544	11		1	12	
9.28.21	Rhoades, Rick	999049	12	1		11	
12/20/21	Return to Supplier	N/A	11	1		10	
4-21-22	Buntow, Carl	000993	10	1		9	
8-17-22	Chanthakoummane, Kosul	999529	9	1		8	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 100 ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
10-5-22	Ramirez, John	999544	8	1		7	[redacted]
11-9-22	Beatty, Tracy	999484	7	1		6	
11-16-22	Barbee, Stephen	999507	6	1		5	
1-5-23	Received from Supplier	N/A	5		8	13	
1-10-23	Fratta Robert	999189	13	2		11	
1-10-23	return to stock	N/A	11		1	12	
2-1-23	Ruiz Wesley	999536	12	1		11	
2-8-23	Balentine, John	999315	11	1		10	
3-7-23	Green Gary	999561	10	1		9	
3-9-23	Brown Arthur	999110	9	1		8	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

EXHIBIT 11

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2,2N,3,3N,4,5,
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 02112021
ORDER FORM 1 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2
BUSINES
STREET
CITY, ST [redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 21 Apr 2021

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50mL	Pentobarbital Sodium Inj 50mg/mL	1	21Apr21	[redacted]	1	4/30/21
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
1	← LAST LINE COMPLETED (MUST BE 20 OR LESS)							

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2,2N,3,3N,4,5,
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 02112021
ORDER FORM 2 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2: TO BE FILLED IN BY PURCHASER

[redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

18 NOV 21
Date

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature, by first supplier [redacted]

11-18-2021
DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50mL	Pentobarbital Sodium Inj. 50mg/mL	1	18NOV21	[redacted]	1	11/18/21
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
1	← LAST LINE COMPLETED (MUST BE 20 OR LESS)							

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2,2N,3,3N,4,5,
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 02/1/2021
ORDER FORM 3 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2: TO BE FILLED IN BY PURCHASER

[redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

21 Dec 2021
Date

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER RECD	DATE RECD	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	100mL	Pentobarbital Injection 50mg/mL	1	24Dec21	[redacted]	1	12/21/2021
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

← LAST LINE COMPLETED (MUST BE 20 OR LESS)

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: CHAIN HOSP/CLINIC
SCHEDULES: 2,2N,3,3N,4,5
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 05062021
ORDER FORM 1 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2: TO BE FILLED IN BY PURCHASER

[redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 06/02/2022

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature - by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50ml	Sodium Pentobarbital (NF) 50mg/ml	1	2/2/22			
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
1	← LAST LINE COMPLETED (MUST BE 20 OR LESS)							

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2,2N,3,3N,4,5,
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 11012021
ORDER FORM 1 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2: TO BE FILLED IN BY PURCHASER

[redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 31Aug22

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

	PACKAGES	SIZE	ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50mL	Pentobarbital Sodium 50mg/mL			[redacted]	1	8/31/22
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
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20								

← LAST LINE COMPLETED (MUST BE 20 OR LESS)

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2,2N,3,3N,4,5,
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 08192022
ORDER FORM 2 OF 3

SUPPLIER DEA NUMBER:# [redacted]

[redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 03OCT22

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50mL	Pentobarbital Sodium Inj. 50mg/mL					
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
1	← LAST LINE COMPLETED (MUST BE 20 OR LESS)							

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-001

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: CHAIN HOSP/CLINIC
SCHEDULES: 2,2N,3,3N,4,5
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 05062021
ORDER FORM 3 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 1/5/2023

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	8	5g	Pentobarbital Sodium 50mg/mL Injection	8	1/5/2023	[redacted]	8	05Jan23
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
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18								
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20								

LAST LINE COMPLETED (MUST BE 20 OR LESS)

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

[redacted]

REGISTRATION INFORMATION

REGISTRATION #: [redacted]
REGISTERED AS: RETAIL PHARMACY
SCHEDULES: 2;2N;3;3N;4;5;
ORDER FORM NUMBER: [redacted]
DATE ISSUED: 08192022
ORDER FORM 1 OF 3

SUPPLIER DEA NUMBER:# [redacted]

PART 2: TO BE FILLED IN BY PURCHASER

BUSINESS NAME [redacted]
STREET ADDRES
CITY, STATE, ZIP

PART 1: TO BE FILLED IN BY PURCHASER

[redacted]

Date 07 Aug 2023

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA # [redacted]

Signature- by first supplie

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER — DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1	1	50mL	Pentobarbital Sodium 50mg/mL	1	8/7/23	[redacted]	1	8/7/23
2								
3								
4								
5								
6								
7								
8								
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← LAST LINE COMPLETED (MUST BE 20 OR LESS)

EXHIBIT 12

CAUSE NO. D-1-GN-22-007149

WESLEY RUIZ, ET AL.	§	IN THE DISTRICT COURTS FOR
	§	
v.	§	TRAVIS COUNTY, TEXAS
	§	
TEXAS DEPARTMENT OF	§	
CRIMINAL JUSTICE, ET AL.	§	345TH DISTRICT COURT

TEMPORARY INJUNCTION

On Tuesday, January 10, 2022, the Court considered the Application for Temporary Injunction sought by Plaintiffs Wesley Ruiz, John Lezell Balentine, Robert Allen Fratta, and Arthur Brown, Jr., (collectively, "Plaintiffs"). Plaintiffs appeared though counsel. Defendants the Texas Department of Criminal Justice, Bryan Collier, Bobby Lumpkin, and Kelly Strong appeared through counsel. The Court finds that proper notice of the hearing was given on January 5, 2022.

The Court grants the plea to the jurisdiction brought by the Texas Department of Criminal Justice because a government entity, as opposed to a government actor, cannot commit an *ultra vires* act. The Court finds that it has jurisdiction over Plaintiffs claims brought against the government actors in their official capacities: remaining Defendants Bryan Collier, Bobby Lumpkin, and Kelly Strong (collectively, "Defendants").

Tthe Court is cognizant of the fact that it is under an order issued by the Texas Court of Criminal Appeals mandating that this court "refrain from issuing any order purporting to stay the January and February executions of Harris County death row inmate Robert Alan Fratta, Dallas County death row inmate Wesley Ruiz, or Potter County death row inmate John Lezell Balentine." As noted below, this Court is not issuing a stay of execution for any of the four Plaintiffs in this case, nor could it. Instead, the Defendants

are enjoined only from committing certain acts while conducting the executions of Plaintiffs.[1]

Defendants objected to the hearing claiming that only Plaintiff Fratta's application for temporary injunction was noticed for hearing, but not the application of the other Plaintiffs. Defendants did not explain the basis of their belief that only one application was noticed for hearing but not another. Further Defendants did not allege or attempt to show any prejudice by hearing the applications together and could not have done so because the applications are seeking identical relief, Defendants filed briefs in response to Plaintiffs' applications for relief, and Defendants received adequate notice of the hearing. The Court overruled that objection because the original and amended notices of hearing together with the applications for temporary injunction made clear that all applications for temporary injunction would be heard together.

Plaintiffs have demonstrated probable irreparable injury for which there is no adequate remedy at law and a likelihood of success on the merits of declaratory judgment actions against the remaining Defendants.

The evidence presented shows that Pentobarbital is a Schedule II controlled substance. Tex. Health & Safety Code § 481.032; Schedule of Controlled Substances, 45 Tex. Reg. 2249 (March 27, 2020).

Defendants' actions in procuring, selecting, storing, and administering Pentobarbital mean that Defendants must comply with the Texas Pharmacy Act under Tex. Occ. Code § 551.003(33). Defendants are not exempted from complying with the Texas

[1] The Court takes judicial notice that Defendants have previously asserted that challenges to an execution protocol are a "civil, not a criminal law matter." *See, e.g., In Re Patrick Henry Murphy, Jr.*, Resps.' Opp. To Relator's Mot. For Leave, No. WR-63,549-02 (Mar. 22, 2019).

Pharmacy Act by Tex. Occ. Code § 551.004 or through Tex. Code Crim. Proc. Art. 43.14.

The Court finds that The Texas Code of Criminal Procedure granting the Defendants discretion does not conflict with the statutes raised by the Plaintiffs. Any discretion granted to Defendants does not mean that Defendants may violate other statutes. Defendants have not shown, nor have they attempted to show, that they cannot comply with the Texas Code of Criminal Procedure without violating the Texas Pharmacy Act, the Texas Health and Safety Code, the Texas Controlled Substances Act, and other statutes. Tex. Code Crim. Proc. Art. 43.14 does not specify what substance or substances that Defendants must use when carrying out an execution. By electing to use a Schedule II controlled substance, Defendants placed themselves under the requirements and regulations of other Texas laws.

Further, the Texas Code of Criminal Procedure Article 43.24 requires that Defendants carry out this duty in such a way that "[n]o torture, or ill treatment, or unnecessary pain, shall be inflicted upon a prisoner to be executed under the sentence of law." Defendants failed to provide evidence or testimony to contradict Plaintiffs' evidence that the expired Pentobarbital will likely cause such torture, ill treatment, or unnecessary pain.

Defendants must also comply with the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code for similar reasons.

Plaintiffs offered unrebutted evidence that the Defendants have not properly stored Pentobarbital in their possession, and that Defendants have not properly disposed of expired Pentobarbital in their possession. Plaintiffs offered unrebutted evidence that all of the Pentobarbital in Defendants' possession is expired and has substantial risk of inflicting

Plaintiffs with harm and unpredictable results. That the Plaintiffs may be lawfully killed by the Defendants soon after suffering this unnecessary and unlawful harm does not negate the appropriateness of this relief.

Defendants did not offer any evidence or witnesses to dispute Plaintiffs' assertions regarding Defendants practices regarding the legality, purity, stability, or microbiology of the Pentobarbital in Defendants' possession. Defendants did not offer any evidence or witnesses to dispute Plaintiffs' assertion that Defendants obtained Pentobarbital without a prescription. Defendants did not offer any evidence or witnesses at all.

The Court finds that the Pentobarbital in Defendants' possession is probably illegal to possess or administer because it is more likely than not expired. The Plaintiffs offered unrebutted evidence that expired Pentobarbital can cause severe harm or unpredictable drug actions. Plaintiffs offered unrebutted evidence that legally compounded Pentobarbital that has been stored for the following time periods since its compounding may be legally administered to them under the Texas Pharmacy Act (the "Storage Conditions"):

- 24 hours, if stored at room temperature between 20° and 25°C;
- 72 hours, if kept refrigerated at temperature range between 2° and 8°C, or
- 45 days, if kept in a solid, frozen state at temperature range -25° and -10°C.

The Court finds that the Plaintiffs' unrebutted evidence shows the following:

1. Expired drugs fall out of solution. That means they become grainy, not liquid. Those crystals, when injected into a vein, cause burning pain in and of themselves. In addition, they can cause blockages in the blood vessels and those blockages are painful.
2. Expired drugs contain degradants. Even if, as Defendants suggest but did not demonstrate with evidence, there remains potent pentobarbital

in the vials, the remaining pentobarbital will not act like pentobarbital in the presence of the degradants.

3. Respondents have handled their pentobarbital with disregard for its purity, stability, and activity in the body in the presence of degradants and contaminants.
4. Degradants form with time, and that Respondent does not test for them. Defendants have reintroduced tested vials into their stocks. Defendants have no way to know whether the testing process introduced organic or other contaminants. That is, Defendants' procedures create a risk of unnecessary pain and unpredictable activity in the body of condemned people.

The Court finds that, unless Defendants are restrained now, Defendants will continue to store and administer expired Pentobarbital that is beyond its use date and that has not had scientifically validated stability and microbiology testing. Defendants would engage in this conduct before the Court can render judgment in this Cause. This storage and administration would cause imminent and irreparable harm to Plaintiffs who have no adequate remedy at law and who would suffer incalculable damage. The Court also finds that Plaintiffs have sought relief expeditiously and have each exhausted their administrative remedies in accordance with Texas Government Code § 501.008(d)(1) or meet an exception to the requirement.

Defendants did not offer any evidence regarding whether they possess any unexpired Pentobarbital in their possession that would meet the Storage Conditions.

The Court further finds that under the circumstances, the balance of equities between Plaintiffs and the Defendants favors the issuance of immediate injunctive relief as it protects Plaintiffs' right to avoid being injected with expired drugs that are likely to cause pain and harm.[2] Accordingly, the Court finds that a temporary injunction is necessary to preserve the status quo between the parties. The Court defines the status quo as a state where the Defendants and those acting in concert with them have not injected the Plaintiffs with Pentobarbital that does not satisfy the Storage Conditions.

IT IS, THEREFORE, ORDERED that, until final judgment is issued by this Court, Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them and who receive actual notice of this order by personal service or otherwise are commanded forthwith to desist and refrain from administering or injecting Plaintiffs with Pentobarbital unless that Pentobarbital is within the number of days specified in the Storage Conditions since the date of its compounding by a pharmacy licensed to compound it.

IT IS FURTHER ORDERED that trial on the merits of this cause is ordered set for March 20, 2023 at 9:00 a.m..

This order shall not be effective unless and until Plaintiffs execute and file with the clerk a bond, in conformity with the law, in the amount of $250.00 dollars.

[2] The Court notes that, independently of this order, Defendants are prohibited from subjecting the Plaintiffs to torture, ill treatment, or unnecessary pain under Tex. Code Crim. Proc. Art. 43.24. The Court finds that continued use of the Pentobarbital in its possession would further violate Defendants' duty to comply with Tex. Code Crim. Proc. Art. 43.24.

The clerk shall forthwith, on the filing by Plaintiffs of the bond, and on approving the bond according to the law, issue a temporary injunction in conformity with the law and the terms of this order.

Signed this 10th day of January 2023.

Catherine A. Mauzy
Presiding Judge